

Remarks

The October 6, 2004 Official Action has been carefully reviewed. In view of the amendments submitted herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, it is noted that a shortened statutory response period of three (3) months was set in the October 6, 2004 Official Action. Therefore, the initial due date for response was January 6, 2005. A petition for a one month extension of the response period is presented with this response, which is being filed within the one month extension period.

As another preliminary matter, it is noted that the Examiner has rejoined claims 3, 20, and 24-26. It is the Examiner's position that claims 20 and 24-26 are directed to methods of producing an allowable product and that claim 3 is a genus of claim 30. The Examiner also indicates that claim 29 has not been rejoined because the claim allegedly does not depend from or otherwise include all of the limitations of an allowable product. Applicants have amended claim 29 to depend from claim 26. Inasmuch as amended claim 29, like claims 20 and 24-26, depends from and includes all of the limitations of an allowable product, Applicants respectfully request that claim 29 be rejoined and fully examined on its merits.

Applicants wish to make clear that they reserve the right to file one or more divisional applications, as provided in 35 U.S.C. §121, directed to the subject matter of the claims held withdrawn from consideration in this application.

At page 3 of the Official Action, the Examiner has maintained the objection to the specification. Specifically, the Examiner maintains that the insertion of "PCT/GB99/02044" at page 7, by virtue of the amendment filed June 25, 2003, is new matter.

Additionally, the objection to claims 10 and 19 under 37 C.F.R. §1.75(c) for allegedly failing to further

limit the subject matter of a previous claim has been maintained. Specifically, the Examiner contends that claim 10 fails to further limit claim 9 and claim 19 fails to further limit claim 18 because the term "reductive domain" is limited to the domains specifically recited in claim 30. Applicants have amended claim 9 and 18 to recite the reductive domains recited in claims 10 and 19. Applicants have also cancelled claims 10 and 19, thereby rendering the instant objection moot. Accordingly, Applicants respectfully request that the objection to claims 10 and 19 under 37 C.F.R. §1.75(c) be withdrawn.

The Examiner has also maintained the rejections of claim 5 under 35 U.S.C. §112, second paragraph for alleged indefiniteness and under 35 U.S.C. §112, first paragraph for allegedly containing new matter. Specifically, it is the Examiner's position the phrase "at least one of the restriction sites included in the polylinker is absent from other naturally occurring nucleic acid sequences which encode reductive domains of Type I polyketide synthases" is indefinite and lacks support in the specification. In the interest of expediting prosecution and without conceding the correctness of the Examiner's position, Applicants have cancelled claim 5, thereby rendering moot the rejections under 35 U.S.C. §112, first and second paragraphs. Accordingly, Applicants respectfully request the withdrawal of these rejections.

Lastly, claim 3 has been rejected under 35 U.S.C. §102(b) for allegedly being anticipated by Eikmanns et al. (Gene (1991) 102:93-98).

The foregoing objections and rejections constitute all of the grounds set forth in the October 6, 2004 Official Action for refusing the present application.

Claims 5, 10, and 19 and withdrawn claims 21-23 have been cancelled. Applicants have also amended claims 3, 9, 18, 26, and 29 in accordance with this amendment. Support for the

amendment to claim 3 is provided in the claim as originally presented, as well as in the specification at page 6, lines 5-11. Support for the amendments to claims 9 and 18 can be found at original claims 10 and 19, respectively. The amendment to claim 26 is of an editorial nature. Lastly, support for the amendment to claim 29 is provided in claim 29 as previously presented. Support for this amendment can also be found in the specification at page 10, lines 7-8 and original claim 23.

No new matter has been introduced into this application by reason of any of the amendments presented herewith.

In view of the present amendment and the reasons set forth in this response, Applicants respectfully submit that the various objections to the specification and claims, the 35 U.S.C. §112, first and second paragraph rejections of claim 5, and the 35 U.S.C. §102(b) rejection of claim 3, as set forth in the October 6, 2004 Official Action, cannot be maintained. These grounds of objection and rejection are, therefore, respectfully traversed.

STATEMENT OF SUBSTANCE OF INTERVIEW

This Statement of Substance of Interview is being submitted in accordance with §713.04 of the Manual of Patent Examining Procedure to make of record a telephone interview held between Examiner Kathleen M. Kerr, Robert C. Netter (Reg. No. 56,422), and the undersigned on or about January 19, 2005 and a subsequent telephone interview on or about January 26, 2005.

An interview was initiated by the undersigned and Robert C. Netter on or about January 19, 2005 for the purpose of discussing certain proposed amendments to claim 3, in an effort to place the claim in condition for allowance. Examiner Kerr requested that the proposed claim amendments be submitted to her for her review. Accordingly, the proposed

claim amendments were transmitted by facsimile by Robert C. Netter to Examiner Kerr on or about January 20, 2005.

A follow-up telephone interview was held on or about January 26, 2005. This interview, which was initiated by Robert C. Netter, was for the purpose of discussing the proposed amendments to claim 3. An agreement was reached with Examiner Kerr on the proposed amendments to claim 3. Claim 3, as presented in this amendment, reflects the agreed upon language for claim 3.

**THE SPECIFICATION HAS BEEN AMENDED TO OVERCOME THE EXAMINER'S
OBJECTION**

The Examiner has maintained the objection to the specification for allegedly containing new matter. Specifically, the insertion of "PCT/GB99/02044" at page 7, by virtue of the amendment filed June 27, 2003, has been considered by the Examiner to be impermissible new matter under 35 U.S.C. §132. The Examiner contends that the specification, as originally filed, only provides a vague title and a filing date which is allegedly insufficient support for the addition by amendment of an application number.

Applicants continue to disagree with the Examiner's finding of new matter on the present facts. Applicants respectfully submit, for the reasons set forth below, that the specification as originally filed provides more than a "vague title and filing date," as stated by the Examiner.

First, the title provided in the original specification is not properly characterized as "vague" because it is, in fact, the exact title of the international patent application as filed.

Second, Applicants note that the specification at page 7, line 26 declares that the application in question is "our copending international patent application." Accordingly, it is clear that at least one of the applicants

of the instant application is also an applicant of the referenced international patent application.

Third, the international patent application is referred to in the instant application as a source for "more details concerning varieties of loading modules" (see page 7, line 25). It is noteworthy that the abstract of the international patent application PCT/GB99/02044, cited in the amendment filed June 25, 2003, refers to certain loading domains of Type I polyketide synthases and swapping them into other Type I polyketide synthases. Applicants submit this reference to the type of disclosure to be found in the international patent application is sufficient to confirm the identity of the international patent application. Indeed, in In re Fouche, the Court of Customs and Patent Appeals found that the incomplete citation "our application No. ____" with reference to an Example I was "reasonably precise" and sufficient to allow incorporation of the application serial number. In re Fouche, 169 U.S.P.Q. 429 (CCPA 1971). The CCPA noted that it was appropriate to look to "the nature of the subject matter disclosed in the earlier application as one means of linking that application to the referring language."

Inasmuch as the instant specification, as originally filed, (1) provides the title of the international patent application (which was not the case in In re Fouche), (2) specifies the filing date of the international patent application (which was not the case in In re Fouche), (3) indicates that at least one of the applicants is the same as at least one of the applicants of the instant application, and (4) identifies the subject matter to be found in the cited reference, Applicants respectfully submit that the original specification provides sufficient information to identify the international patent application and allow the addition of the application number to the specification.

However, in the interest of expediting prosecution of the instant application, Applicants have amended the

specification to remove the alleged new matter. Inasmuch as loading modules were known at the time the instant application was filed, Applicants submit that the deletion of this reference does not raise any issues of enablement or written description/new matter.

In light of the foregoing, Applicants respectfully request that the objection to the specification for allegedly containing new matter be withdrawn.

CLAIM 3, AS AMENDED, IS NOT ANTICIPATED BY EIKMANNS ET AL.

The Examiner has rejected claim 3 under 35 U.S.C. §102(b) as allegedly anticipated by Eikmanns et al. (Gene (1991) 102:93-98). The Examiner has taken the position that the term "at least part of," when referring to a nucleic acid molecule, reads on as little as a single nucleotide. The Examiner asserts that Eikmanns et al. teach plasmids comprising multiple restriction sites and that these plasmids, therefore, read on claim 3.

Applicants have amended claim 3 to be dependent from claim 30. Accordingly, claim 3, as amended, is drawn to isolated recombinant nucleic acid molecules encoding a Type I polyketide synthase, wherein a portion corresponding to at least one reductive domain of the polyketide synthase has been replaced with a polylinker region comprising multiple restriction enzyme sites, wherein the polylinker region connects a nucleic acid sequence, which encodes at least part of an acyl transferase domain, to a nucleic acid sequence which encodes at least part of an acyl carrier protein domain.

In contrast, Eikmanns et al. teach only cloning vectors, expression vectors, and promoter probe vectors which comprise multiple restriction sites (see Abstract). Nowhere in Eikmanns et al. is there any teaching of nucleic acid molecules encoding a Type I polyketide synthase as recited in amended claim 3 of the instant application.

Inasmuch as Eikmanns et al. fail to teach each and every aspect of the instantly claimed invention, Applicants

submit that the rejection of claim 3 under 35 U.S.C. §102(b) as allegedly anticipated by Eikmanns et al., has been overcome. Accordingly, Applicants respectfully request that the rejection be withdrawn.

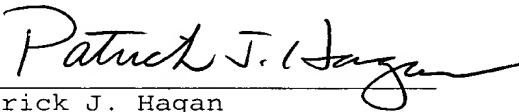
CONCLUSION

In view of the amendments presented herewith, and the foregoing remarks, it is respectfully urged that the objections and rejections set forth in the October 6, 2004 Official Action be withdrawn and that this application be passed to issue.

In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to telephone the undersigned attorney at the phone number given below.

Respectfully submitted,
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